

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Comments on FDA Draft Affirmative Agenda
for International Activities

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Docket Number 99N-3089

Comments of the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

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Food and Drug Administration
5630 Fishers Lane
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Re: Draft Affirmative Agenda for International Activities
Food And Drug Administration's Center for Food Safety and Applied Nutrition
64 Fed. Reg. 50518, September 17, 1999.

The Center for Science in the Public Interest ("CSPI")¹ submits these comments on the Draft Affirmative Agenda for International Activities ("Agenda") of the Center for Food Safety and Applied Nutrition ("CFSAN") of the Food and Drug Administration ("FDA").

Introduction

The Draft Agenda asserts (at 1) that CFSAN faces a "dilemma" because other parts of the Administration "and other stakeholders" want its assistance on subjects relating to international trade that go beyond CFSAN's explicit statutory obligations. This so-called dilemma is easily solved -- CFSAN's international activities should be limited to the statutory priorities that Congress has assigned to the FDA. Those who want CFSAN to undertake other activities should

¹ CSPI, a nonprofit organization based in Washington, D.C., is supported by approximately one million members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the public's health through better nutrition and safer food since 1971. CSPI is a recognized observer at the Codex Alimentarius Commission and is a founding member of the International Association of Consumer Food Organizations.

demonstrate to Congress the need to provide the FDA with additional resources and legal authority.

Our comments on the specific proposed priorities follow in the order presented in the Agenda. Our comments, however, are severely handicapped by not knowing how much time and money CFSAN is currently spending on each of these international activities. We urge CFSAN to promptly make such information available.

I. Regulatory (Enforcement, Monitoring, Inspection Activities)

The Agenda divides this area into four activities: (1) monitor imported foods, (2) inspect foreign establishments, (3) trace food-borne illness outbreaks associated with imported foods and prevent future outbreaks, and (4) improve food labeling compliance for imported foods.

It is crucial that CFSAN's priorities not be diverted to international activities on the fringe of its statutory mandate because CFSAN does not even have enough resources to fulfill its primary statutorily mandated international activity -- ensuring the safety of imported food.² In

² Congress has authorized three additional specific FDA international activities in the food area. Section 803(c)(1) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") says that the FDA shall support the activities of the United States Trade Representative ("USTR") in its efforts "to reduce the burden of regulation and harmonize regulatory approaches *if* the Secretary determines that such harmonization continues consumer protections consistent with the purposes" of the FFDCA (emphasis added). Section 803(c)(2) of the FFDCA says that the FDA shall support the USTR in its efforts to move toward the acceptance of "mutual recognition agreements" for food and other products between the European Union and the United States. Section 803(c)(3) of the FFDCA says that the FDA shall regularly meet with representatives of other foreign governments to try to harmonize regulatory requirements.

The Senate Committee report explaining these provisions says "The committee intends and specifically instructs the FDA to promote and protect the health of the American public in implementing the" mutual recognition agreement that the Administration was then negotiating with the European Union. The Committee goes on to say "The committee looks forward to seeing more global partnership in the form of a quality mutual recognition agreement that

approving the FDA's FY 2000 budget, Congress has reaffirmed the paramount importance of safety. The House of Representatives Committee on Appropriations said "The agency's mission and sole objective is to protect and promote the public health..."³ The Senate Committee on Appropriations said "The mission of the Food and Drug Administration is to ensure that: (1) food is safe, pure, and wholesome; . . ."⁴

In order to carry out its mission to ensure that food is safe, section 801 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") authorizes the FDA to sample imported food. However, as the General Accounting Office reported in 1998, while the number of imported food shipments more than doubled between 1992 and 1997 to 2.7 million, the FDA resources devoted to inspecting imported food fell by 22 percent.⁵ According to FDA, each import inspector now handles almost twice the workload of just five years ago.

The percentage of imported food shipments inspected by the FDA fell from 8 percent in FY 1992 to 1.7 percent in FY 1997.⁶ The percentage of sampled foods that is sent to a laboratory to be tested for harmful contaminants is even smaller. In 1997, this number barely exceeded one-half of one percent.

complements both our high public health and safety standards in the United States and appropriate international regulatory controls." S. Report 105-43 (1997) at 19.

³ H. R. Report 106-157 (1999) at 91.

⁴ S. Report 106-80 (1999) at 123.

⁵ General Accounting Office, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable* (April 1998) at 25.

⁶ By contrast, the United States Department of Agriculture ("USDA") has enough resources so that it can sample 20 percent of imported meat and poultry to determine if it is safe. *Id.* at 17.

These figures are particularly disturbing given that viruses, parasites, and bacteria are showing up with alarming frequency on fruits and vegetables imported from other countries. In recent years, food-borne illness outbreaks have been linked to viruses on strawberries from Mexico (which were served in the school lunch program), parasites on berries from Guatemala, and bacteria on carrots from Peru.

Furthermore, bacteria, viruses, and parasites that contaminate imported foods can be different from our home-grown varieties. This fact can prolong the time it takes to identify novel sources of tainted food ingredients and treat the causes of illnesses.

The FDA must increase its inspection of imported food and must send inspectors to foreign countries to check their food safety programs and food processing plants, just as the USDA does today for imported meat and poultry products. More resources also must be dedicated to facilitating the development of new technology for rapid testing of foods for harmful bacteria, viruses, and parasites.

While Congress has approved a FY 2000 budget for CFSAN of \$269 million (a 15 percent increase over the FY 1999 level of \$233 million), it is very doubtful that CFSAN's budget will permit it to sample imported food at the same rate that the USDA does. Thus, CFSAN cannot afford to spend resources on matters unrelated to its core mission and instead must focus on its statutory mandate of ensuring the safety of consumers.

II. International Harmonization

The Agenda divides this area into five activities: (1) strengthen CFSAN participation and leadership in the Codex Alimentarius Commission ("Codex"), (2) participate in the Codex

biotechnology task force, (3) contribute scientific expertise towards the development of international standards, (4) participate in the North American Free Trade Agreement (“NAFTA”) and the Free Trade Area of the Americas (“FTAA”) technical committees and working groups, and (5) participate in other standard setting bodies.

Many of the harmonization efforts in which CFSAN is currently involved are out of step with the FDA’s core mandate to protect the public health because these efforts result in the development of international standards that may lead to downward harmonization of U.S. health and safety rules. Such standards are typically negotiated in international forums where government officials strive to increase trade by developing mutably acceptable health and safety standards that benefit business interests from their nations. Such standards are often based on the lowest common denominator that is mutually acceptable to all negotiating parties, including less-developed countries that, in the absence of increased technical assistance, cannot comply with world-class requirements. This entire process will likely lead to downward harmonization of U.S. regulatory requirements, thus providing American consumers with less protection than they now receive.

Section 803(c)(1) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”) states that the FDA shall support the activities of the United States Trade Representative (“USTR”) in its efforts “to reduce the burden of regulation and harmonize regulatory approaches *if the Secretary determines that such harmonization continues consumer protections consistent with the purposes*” of the FFDCA (emphasis added).

This requirement indicates that food safety and consumer protection must not be sacrificed in the name of harmonization. As President Clinton stated in a 1998 speech reflecting

the Administration's policy concerning international harmonization of regulatory standards:

We must build a trading system for the 21st century that honors our values as it expands opportunity. We must do more to make sure that this new economy lifts living standards around the world, and that spirited economic competition among nations never becomes a race to the bottom in environmental protections, consumer protections and labor standards. We should level up, not level down.⁷

Thus, CFSAN's international harmonization activities must be limited to maintaining current U.S. standards, or raising U.S. standards to international levels that would afford American consumers even greater protection than they are currently provided. Unfortunately, that is not the case today.

1. Strengthen CFSAN Participation and Leadership in Codex

Since 1994, Codex standards have carried legal significance within the U.S. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)⁸ encourages nations to base domestic regulatory standards on international standards developed by Codex. Domestic regulatory requirements that are based on Codex standards are presumed to be consistent with the SPS Agreement,⁹ while those that differ from Codex standards may be challenged as trade barriers. A domestic health standard is illegal under the SPS Agreement if the WTO decides that it is not "based on scientific principles and is...maintained without sufficient scientific evidence." If the WTO finds that a country has

⁷ President William Jefferson Clinton, Statement to the World Trade Organization (June 1998).

⁸ GATT Doc. MTN/FA II-A1A-4 (Dec. 15, 1993) in *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, GATT Doc. MTN/FA (Dec. 15, 1993) 33 I.L.M. 9 (1994).

⁹ *Id.* at Article 3.2

erected a trade barrier, the country must either lower its regulatory requirements to comply with the Codex standard or pay reparations to the complaining country.

While, in principle, the U.S. is free to defend its domestic health and safety regulations at the WTO on the basis of science, the reality is that we would face a sizable legal hurdle. Mounting a defense would be difficult, resource intensive, burdensome, and risky. In many cases, the Administration may simply decide to give in to pressure and quietly waive U.S. regulatory requirements for imported foods especially if important trade considerations are involved in the dispute. Even if a WTO defense were mounted, the U.S. could lose. That is exactly what has happened in several cases involving U.S. environmental protection regulations brought by developing countries under other provisions of the WTO agreement.

Incremental improvements in the health and safety standards of developing countries, brought about by the adoption of Codex standards, may help such nations progress and enter the international marketplace. However, the health of Americans is not well served if the United States is pressured by the WTO to allow the marketing of products meeting Codex standards that offer consumers less protection than that provided by current FDA rules.¹⁰

Because of the legal significance of Codex standards and their potential to weaken U.S. regulatory requirements, CFSAN must strengthen its leadership in Codex. It is essential that CFSAN's participation in Codex is fully consistent with its public health mandate and is focused on protecting the health and safety of American consumers rather than promoting the food

¹⁰ Portions of this problem stem from the very nature of the SPS Agreement. The SPS only permits challenges if domestic standards exceed international standards -- the Agreement fails to provide any incentives for standards higher than those set by Codex. In addition, the SPS builds in special consideration for the needs of developing countries that cannot meet high health and safety standards.

industry's interest in facilitating trade through the establishment of uniform regulatory requirements based on weak standards. Accordingly, we recommend that CFSAN's participation in Codex be guided by the following five points:

a. CFSAN should vigorously oppose the development of all Codex standards that are weaker than U.S. regulations.

Most Codex proceedings operate by consensus where representatives of member nations work to facilitate the development of final Codex standards. In many situations, the U.S. has supported Codex committee decisions calling for the finalization of standards weaker than those required by the U.S. This procedure may have made sense when the U.S. was simply providing technical expertise to Codex in order to benefit less developed countries that had no health or safety standards at all. However, this approach to Codex proceedings no longer serves the interests of American consumers. Members of the U.S. delegation from CFSAN should be instructed to officially object to the development of any Codex standard that falls below U.S. regulatory requirements.

Unfortunately, many of the proceedings of the Codex Alimentarius Commission concerning the SPS Agreement have become forums for deregulation and have resulted in the adoption of numerous health and safety standards that are significantly weaker than those required in the U.S. (See Attachment 1):

- Codex adopted an international safety standard for natural mineral water that permits higher levels of lead and other contaminants than the FDA allows;
- Codex adopted an international standard for food safety inspection systems that permits self-evaluation by companies or non-governmental third-parties, even though food safety inspections in the United States are the responsibility of the FDA and state governments;

- Codex approved pesticide residue levels that do not take into account the health effects of pesticides on children, as mandated under U.S. law;
- Codex approved a safety standard for dairy products that does not require pasteurization even though pasteurization of dairy products is generally required by the FDA;
- Codex sanctioned the use of five food additives which have not been formally approved by the FDA for use in the United States;
- Codex approved an international standard that permits composite ingredients at levels of 5% or less to be listed by a standardized name without declaring all of its component ingredients, even though the FDA requires these component ingredients (except for flavors, natural colors, and certain other substances) to always be listed in order to protect consumers who suffer from hypersensitivities;
- Codex defeated attempts to strengthen current Codex nutrition labeling requirements to make them more akin to U.S. law.

Thus, CFSAN should seriously consider whether its participation in Codex is facilitating international trade at the expense of subjecting American consumers to the possibility of being pressured by the WTO to accept imported foods that do not meet FDA standards.

The USTR has stated that while harmonization of international standards contributes to the removal of unnecessary trade barriers, the SPS Agreement “makes clear that it does not require ‘downward harmonization’” of health and safety standards in order to meet that objective.¹¹ The U.S. has taken the position that no WTO member is required to adopt an international standard if doing so would result in a level of protection determined to be inappropriate by that member.¹² As commentators have widely recognized, however, there is the

¹¹ 62 Fed. Reg. 64,619 (1997).

¹² White House Office of the Special Trade Representative, *Statement of Administrative Action-Agreement on the Application of Sanitary and Phytosanitary Measures*, Section A(7).

danger that whenever an international standard is less stringent than an existing U.S. regulation, American consumers face the risk that the domestic regulation will be lowered. As one leading commentator has stated:

The Agreement on S&P Measures clearly has the potential for affecting some American regulations. For example, the standards for risk assessment established by American regulatory statutes vary widely, ranging from zero risk in the case of food additives covered by the Delaney Clause to more flexible limits for pesticide residues established by the EPA. Moreover, American nutritional labeling requirements are more extensive than the Codex voluntary food labeling guidelines. Clearly, most of the impact of the S&P Agreement will depend on precisely which of the American regulatory requirements that exceed those established by the Codex Commission are challenged in WTO dispute settlement proceedings and the way the Committee on S&P measures interprets the various provisions of the Agreement.¹³

For example, Venezuela challenged Environmental Protection Agency (EPA) regulations on gasoline quality at the WTO. In 1997, the WTO ruled in favor of Venezuela, and the EPA subsequently changed its regulations, weakening its ability to enforce federal air quality standards.¹⁴ Another WTO ruling last year undermined the Endangered Species Act when the WTO ruled that the U.S. requirement that shrimp fishing boats install devices that allow sea turtles to escape the nets is unfair to other countries.

While these cases did not involve the SPS Agreement, they are indicative of what could happen if a foreign government challenges FDA rules at the WTO. Indeed, the European Union

¹³ David Vogel, *Trading Up: Consumer and Environmental Regulation in a Global Economy*, 192-193 (1995). Another commentator has stated: "The danger lies in the fact that, whenever a Codex standard is more tolerant..than a national standard..consumers in that country face an increased risk that the national standard will be lowered to prevent trade controversy." Bartlett Miller, *The Effect of NAFTA and GATT on Pesticide Regulation: A Hard Look at Harmonization*, 6 Colo. J. Int'l Env'tl. L. & Pol'y 201, 218 (1995).

¹⁴ Statement by the delegation of the European Union at the Conference on the International Food Trade Beyond the Year 2000, October 13, 1999, Melbourne Australia.

just recently repeated allegations that the FDA's mandatory nutrition labeling requirements (which exceed Codex standards) constitute an illegal trade barrier. It may be only a matter of time before a country cites a Codex standard as evidence that an FDA regulatory requirement is unreasonably high, successfully challenges the FDA regulation as a trade barrier, and compels the FDA to lower its regulation to the international level.

b. CFSAN should build a record to defend against potential trade complaints based on Codex standards that are weaker than U.S. regulatory requirements.

If CFSAN cannot successfully block the development of final Codex standards that are weaker than FDA regulatory requirements, then it should make a concerted effort to record its position in the reports of Codex proceedings to establish a record that clearly demonstrates why the U.S. believes the Codex standard does not accord sufficient protection to consumers. The most effective way of establishing such a record is for the U.S. delegation to call for a vote on standards that fall below U.S. regulatory requirements and to file dissenting views in situations where the U.S. does not prevail. The building of such a record will help discourage potential trade complaints and serve as a basis for a defense before the WTO in the event that any complaints are brought.

c. CFSAN should object to the addition of new agenda items that could lead to a weakening of U.S. regulatory requirements.

CFSAN should take a more proactive role in determining which items are placed on the agendas of Codex committees. CFSAN should object to a new agenda item if it will likely lead to a standard which is weaker than U.S. regulatory requirements because other nations could use the Codex standard as the basis for a complaint to the WTO alleging that the U.S. requirement

constitutes a barrier to trade.

An example is the current effort to reform Codex standards for nutrition labeling. Because the United States and Israel are the only nations in the world that currently have requirements for mandatory nutrition labeling of foods, it is unlikely that any new standard for nutrition labeling produced by Codex would include a mandatory nutrition labeling requirement. If a new Codex standard that does not call for mandatory nutrition labeling were developed, other nations would be able to use the Codex standard as a basis for a complaint to the WTO alleging that the U.S. requirement for mandatory nutrition labeling constitutes a barrier to trade. It is therefore in the best interest of the U.S. to oppose the consideration of a new Codex standard for nutrition labeling.

d. CFSAN's participation in Codex should be used as an opportunity to raise current FDA standards.

In a few instances, international harmonization activities may provide opportunities for CFSAN to *raise* current FDA regulatory standards. Unfortunately, the agency has not taken advantage of such opportunities in the past.

For example, in June 1999, Codex established a standard establishing a maximum tolerable level for aflatoxin, a naturally occurring carcinogen in mold that grows on peanuts. The FDA currently permits 20 $\mu\text{g}/\text{kg}$. The European Union (EU) had fought for a lower level of 10 $\mu\text{g}/\text{kg}$. The U.S. could have taken this opportunity to lower the U.S. action level to meet the level favored by the EU. Instead the U.S., taking the position that a 10 $\mu\text{g}/\text{kg}$ ceiling did not offer significant health benefits and constituted a trade barrier, pressured Codex members to support a less strict maximum level. The EU and other countries ultimately gave in to pressure

from the U.S. and Codex adopted the 15 µg/kg standard.

At the same meeting, the Codex Committee on Food Labeling proposed an amendment to the current Codex standard for frozen fish sticks that would require the percentage of fish core to be stated on the label. The FDA, which could have taken this opportunity to support percentage ingredient labeling, did not speak in favor of the amendment and Codex failed to approve it.

The Codex Committee on Nutrition and Foods for Special Dietary Use has discussed the possibility of developing a guidance document on the sale of potentially harmful herbal products and also discussed using trans fat as a component of saturated fat for the purpose of making nutrition claims. Although those proposals could have provided an impetus for the FDA to strengthen its regulations by upwardly harmonizing with international standards, the U.S. opposed both proposals at the time they were made.

e. CFSAN should urge the Codex Committee on General Principles to create procedures for the development of non-binding Codex standards.

As an alternative to opposing a weaker standard, the U.S. could urge Codex to re-designate a standard as a non-binding “advisement” which does not carry the force of law and would not raise the possibility that domestic regulations would be lowered in response to objections raised by the WTO. This would allow the U.S. to continue to support the goals of international harmonization while protecting the interests of American consumers.

In fact, the Chairman of the WTO’s General Council, Ali Mchumo, stated in his October 11, 1999 Draft Declaration for the WTO Ministerial Meeting scheduled to begin in Seattle on November 30, that the definition of an international standard, guideline, and recommendation, as referred to in Article 3 of the SPS Agreement, “needs to be revised so that a differentiation is

introduced between mandatory international standards and voluntary international guidelines/recommendations.” “Standards” should refer only to those decisions made by a virtually unanimous Codex, while other Codex decisions should be considered as “guidelines” or “recommendations.”

2. Participate in the Codex Biotechnology Task Force

CFSAN’s participation in the Codex biotechnology task force should be limited to those areas promoting the public health of American consumers -- not promoting a particular food technology in order to increase U.S. agricultural exports. If the purpose of the Codex Biotechnology Task Force is solely to promote the trade of bioengineered foods, FDA participation in the task force should be discontinued until CFSAN finds appropriate funding for such efforts.

3. Contribute Scientific Expertise Toward Development of International Standards

We support CFSAN’s efforts in contributing scientific expertise, so long as CFSAN’s contributions aid in developing international standards in an upward, not downward, fashion and do not undermine current domestic regulatory requirements.

4. Participate on NAFTA Committees/Technical Working Groups

The FDA is the lead agency for four of the eight Technical Working Groups (“TWGs”) established by the NAFTA Sanitary and Phytosanitary (“SPS”) Committee: Fish & Fishery Product Inspection; Dairy; Fruits, Vegetables and Processed Foods; Veterinary Drugs & Feed; and Food Additives and Contaminants. The FDA has stated that the Fish and Fishery Product Inspection TWG plans to continue discussions on a United States-Canada Mutual Recognition Agreement (“MRA”) on seafood inspection and a United States-Canada equivalence agreement

regarding a molluscan shellfish inspection program.¹⁵ Such discussions should be continued only if their sole goal is to develop agreements that harmonize the two countries' seafood safety programs in an upward fashion by combining the best elements of each country's system. Presently, the Canadian program provides numerous benefits over the FDA's. This area thus represents an opportunity for FDA to harmonize requirements upward by raising its requirements to the level of Canada's requirements. The FDA should not participate in such discussions if a possible outcome is to weaken seafood food safety in either country in order to facilitate trade between the two countries.

5. Participate in Other Standard Setting Bodies

We support CFSAN's participation in other standard setting bodies only on the condition that CFSAN's participation encourages the upward harmonization of international standards bearing on the safety and quality of FDA-regulated products and does not undermine current domestic regulatory requirements.

III. Development, Maintenance, and Dissemination of CFSAN's Science Base

The Agenda divides this area into four activities: (1) participate in international scientific consultations and panels, (2) strengthen scientific collaboration with foreign governments, (3) strengthen research and risk assessment activities, and (4) investigate alternatives to animal testing.

We support these activities only to the extent that they lead to upward harmonization of regulatory requirements. Presently, some such efforts are conducted to try to convince foreign

¹⁵ 64 Fed. Reg. 49268 (September 10, 1999).

governments that the FDA's particular approach to a regulatory problem is correct in an attempt to pressure the foreign government to accept exports from the U.S. that it deems unsafe. This trade related function should not be performed by FDA absent a new mandate and additional resources from Congress.

IV. Equivalence Evaluations, Food Safety Needs Assessments, and Food Safety Technical Cooperation and Assistance

The Agenda divides this area into three activities: (1) determine equivalence of food safety systems of other countries, (2) assess the food production and food safety systems of other countries, and (3) improve the safety of imported foods at their source.

In 1994 Congress authorized the FDA to determine that a foreign food safety system is equivalent to that required pursuant to the FFDCA if the FDA "determines that the sanitary or phytosanitary measures of the foreign country provides at least the same level of" protection as the measures established by the FDA.¹⁶ So far, the FDA has not made no such determination. It is quite possible that the quest for food safety "equivalence" is chimerical. We note that the USDA has been unable to determine whether any foreign country's salmonella testing system for meat and poultry provides a level of safety "equivalent" to the salmonella testing announced by the USDA in July 1996. CFSAN should thus concentrate on assessing the safety of foreign food production and improving safety in those countries that now provide less protection than the FDA's domestic requirements.

We further call upon the FDA to use notice and comment procedures for the development

¹⁶ Section 432 of the Uruguay Round Agreement Act, P.L. 103-465, amending Title IV of the Trade Agreements Act of 1979. 19 U.S.C. §§2531 et seq.

of any equivalency agreements into which it does enter. We oppose the shortcutting of the administrative process by developing mutual recognition agreements. These agreements serve the same purpose of an equivalency agreement, but are often not developed with the benefit of public comment.

V. International Trade Agreements and Other Trade-Related Activities

The Agenda divides this area into four activities: (1) provide FDA Policy and Technical Guidance to World Trade Organization (“WTO”) and NAFTA Committees on Sanitary and Phytosanitary Measures (SPS Committee), (2) assist U.S. Trade Agencies, (3) issue certificates of export to U.S. food and cosmetic producers and exporters, and (4) develop a way for the FDA to attest to the safety of certain animal-derived foods.

The first activity is required by Congress, as set forth in section 803(c)(3) of the FFDCA. But, this requirement must be read in light of the other requirements of the Act that concern the FDA’s core mission to protect the public health. The FDA should not provide technical advice if it will have the effect of weakening food safety standards in the United States in order to facilitate international trade.

Section 803(c)(1) of the FFDCA authorizes the second activity *only* “if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act.” FDAMA § 410(c), 21 U.S.C. § 383(c). The USTR, however, is interested in promoting United States exports in foreign countries even at the expense of sacrificing consumer protection. For example, in the summer of 1999 the USTR wrote to the European Commission that there was no scientific justification for the EU’s ban on using antibiotics used in human

medicine as growth promoters in livestock. The USTR ignored the fact that the European Union's ban was consistent with the 1997 recommendation of the World Health Organization and failed to recognize that the Centers for Disease Control had concluded that the EU's ban is scientifically justified. Thus, the FDA should stop providing assistance to the USTR until the Secretary publicly makes the determination that the statute requires.

Congress has directed the FDA to issue export certificates for drugs, animal drugs, or devices, and the FDA is authorized to charge up to \$175 for such a certificate.¹⁷ There is, however, no statutory mandate to issue such certificates for food and cosmetics and no authority for the FDA to charge a fee for issuing a certificate for food and cosmetics. At the present time, the FDA is providing such letters to food manufacturers on request, and is attempting to recoup the expenses incurred in issuing the certificates.¹⁸ The agency, however, should discontinue this practice (whose sole purpose is to increase United States exports) in the absence of an express statutory mandate that permits the agency to charge a user fee reflecting the full cost of administering the program as it relates to foods.

In brief, CFSAN cannot and should not perform the function of a trade mission -- its resources should be devoted to protecting the health of American consumers.

Conclusion

CFSAN must conserve its limited resources for its core mission -- protecting the health of American consumers. Neither CFSAN, nor the agency as a whole, has sufficient resources for

¹⁷ Section 801(e)(4) of the FFDCA, 21 U.S.C. § 381(e)(4).

¹⁸ Compliance Policy Guide 7150.01.

functions such as facilitating trade, increasing U.S. exports, or assisting international scientific bodies, unless those activities directly further the agency's core mission. Unfortunately, that is not the case today -- CFSAN has been side-tracked from its core duties and is engaging in numerous international activities that have little or no bearing on protecting the health of Americans. Indeed, as demonstrated here, some of these activities may lead to a lowering of public health standards in the U.S. CFSAN must therefore reevaluate its international program to bring it into line with the FDA's core mission -- to protect and promote the public health.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bruce Silverglade", written in a cursive style.

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